

**IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA  
AT CHARLESTON**

<b>IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION</b>	<b>Master File No. 2:12-MD-02327 MDL 2327</b>
<b>THIS DOCUMENT RELATES TO: ETHICON WAVE 1 CASES</b>	<b>JOSEPH R. GOODWIN U.S. DISTRICT JUDGE</b>

**DEFENDANTS' MOTION TO EXCLUDE PEGGY PENCE, PH.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon"), pursuant to Fed. R. Evid. 702 and *Daubert v. Merrell Dow Pharms.*, Inc., 509 U.S. 579, 589 (1993), move to exclude the testimony of Peggy Pence, Ph.D., in the entirety. In support of this motion, Ethicon states:

1. Dr. Pence is not qualified to opine about the adequacy of the device IFUs, and her methodology is unreliable.
2. Dr. Pence is not qualified to opine that Ethicon did not meet the post-market vigilance standard of care for TVT, TTVT-O, and Prolift; her methodology is unreliable; and her opinion is irrelevant.
3. Dr. Pence is not qualified to offer opinions about the adequacy of the TTVT, TTVT or PROSIMA testing. In addition, Dr. Weber offers a number of unreliable and irrelevant opinions throughout her expert report.
4. Dr. Pence's opinion that the TTVT-O and PROSIMA labeling did not support adequate informed consent of patients is irrelevant and inadmissible.
5. Dr. Pence's opinion that Ethicon obtained clearance to market PROSIMA based

on false or misleading statements to the FDA is speculative, irrelevant, and inadmissible.

6. Dr. Pence's opinion that Ethicon did not act in the interest of patient safety is unreliable and irrelevant and should be excluded.

7. Ethicon incorporates by reference its Memorandum in Support of its Motion to Exclude Peggy Pence, Ph.D., and the following exhibits:

<b>Exhibit</b>	<b>Description</b>
A	List of Applicable Cases
B	Dr. Pence's Prolift Report, July 17, 2014
C	Dr. Pence's TVT-O Report, July 17, 2014
D	Dr. Pence's TVT Report, Oct. 14, 2013
E	Dr. Pence's PROSIMA Report, Feb. 1, 2016
F	Dr. Pence's Supplemental TVT and TVT-O Report, Mar. 2, 2016
G	Dr. Pence's Supplemental Prolift and PROSIMA Report, Mar. 3, 2016
H	Transcript of Dr. Pence's Mar. 24, 2016 Deposition
I	<i>Label and Instructions for Use for Medical Devices, Global Harmonization Task Force, Sept. 16, 2011</i>
J	<i>Device Labeling Guidance #G91-1 (Blue Book Memo), FDA Office of Device Evaluation, Mar. 8, 1991</i>
K	Transcript of Dr. Pence's Mar. 3, 2016 Deposition
L	Plaintiffs' Designation and Disclosure of General and Case-Specific Expert Witnesses

WHEREFORE, FOR THESE REASONS and as more fully set forth in Ethicon's supporting memorandum of law, Ethicon respectfully requests that this Court enter an order granting Ethicon's Motion to Exclude Peggy Pence, Ph.D.

Respectfully submitted,

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**CERTIFICATE OF SERVICE**

I, Christy D. Jones, certify that on April 21, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

/s/ Christy D. Jones  
Christy D. Jones

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